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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/648,047	08/26/2003	Bill H. McAnalley	MANN:1003RCE	3228
34725 7590 12/09/2010 CHALKER FLORES, LLP 2711 LBJ FRWY Suite 1036 DALLAS, TX 75234				
EXAMINER				
FRITCHMAN, REBECCA M				
ART UNIT		PAPER NUMBER		
1777				
MAIL DATE		DELIVERY MODE		
12/09/2010		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/648,047

**Applicant(s)**

MCANALLEY ET AL.

**Examiner**

REBECCA FRITCHMAN

**Art Unit**

1777

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 25 October 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1, 5, 8, 11-22 and 36 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 5, 8, 11-22, & 36 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Summary*

This is the Non-Final Office Action based on the 10/648047 RCE filed 10/25/2010.

Claims 1, 5, 8, 11-22, & 36 are pending and have been fully considered.

### Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

**1. Claims 1, 5, 8, 11-22 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fleischner (USP 6,291,533) in view of Brand et al. (An Outstanding Food Source of Vitamin C, The Lancet, Vol. 320 Issue 833, p. 873) and further in view of Cho et al. (US Pub 2002/0192314).**

Fleischner teaches an antioxidant composition comprising a flavonoid such as isoflavone or a flavonol such as quercetin, a mixture of two forms of Vitamin E, Vitamin C, polyphenols, green tea extract and a carrier such as aloe vera gel extract (columns 7-8).

Fleischner teaches a ratio of flavonoid or analog to mixture of vitamin E forms as 40/60 to 90/10 percent by weight (column 8 lines 42-63). In the demonstrated tablet in

column 8, the flavonoids equal approximately 245.5 mg, (120 mg Quercetin, 20 mg soy isoflavones, 80 mg silymarin, 7.5 mg flavonoids in Hawthorne berry, 18 mg catechin) and the Vitamin E equals approximately 133 mg. This mixture of flavonoid and Vitamin E forms are present in the composition in a weight ratio of approximately 65/35, respectively, falling into the claimed ratio. Fleishchner also teaches that Quercetin is a powerful antioxidant that is known to reduce the risk of stroke (column 7 line 36). It would have been obvious for one of ordinary skill in the art to make a tablet containing a 30% weight percentage of quercetin and vitamin E forms in order to make a tablet that has a stronger ability to reduce risk of stroke.

Fleischner does not teach a source of vitamin C and does not disclose a composition additionally comprising bush plum pulp and skin comprising 5% vitamin C. Brand et al. disclosed in 1982 that bush plum pulp and skin is an outstanding source of Vitamin C (p.873). Thus, one needs only a small amount of this fruit to meet the daily requirements of vitamin C. Adding an ingredient with a high proportion of the nutrient is ideal for nutritional supplements as it keeps the size of the supplement small while adding a higher concentration of the desired ingredient. It would have been obvious for one of ordinary skill in the art to modify Fleischner with the teachings of Brand et al. by using the edible parts of bush plum as the source of vitamin C so as to keep the size of the supplement small while adding enough vitamin C to meet the intended nutritional requirements. While Brand et al. do not teach a percentage of vitamin C of 5% in the edible fruit, it is within the knowledge of one with ordinary skill in the art to modify the percentage of a nutrient in an ingredient for the desired effect.

Fleischner and Brand do not disclose a supplement additionally comprising grape skin extract comprising 30-82% polyphenols. Cho et al. teaches a dietary supplement comprising grape skin extract ([0012]) comprising polyphenols of between 25 and 100%, within applicant's disclosed range ([0016]). CHO et al. also teach of the a dietary supplement which in addition to grape seed extract contains, tocopherol(vitamin E), ascorbic acid(vitamin C)(paragraph 0028), polyphenols(paragraph 0004),and flavanols(paragraph 0005).

Grape skin extracts have known antioxidant properties, specifically known to inhibit LDL cholesterol oxidation ([0012]). It would have been obvious to modify the teachings of Fleischner by adding grape skin extracts in 25-100% polyphenols order to gain the advantages of the antioxidant properties. Also, it would have been obvious to one of ordinary skill in the art to combine FLEISCHNER, BRAND, and CHO since there is a need for pharmalogic and nutritional interventions that are useful for preventing the reoccurrence of conditions such as coronary artery disease"(CHO, paragraph 0003). Further, it would have been obvious to have grape skin and green tea extracts present in a weight ratio of from 60/40 to 80/20 percent in order to optimize a result-effective variable. The benefits of both are known and it would have been obvious to find the ideal percentage composition of grape skin and green tea in order to maximize the antioxidant benefits of these components. In the absence of unexpected results, the claimed weight ratio would have been obvious to one of ordinary skill in the art.

***Response to Arguments***

Applicant's arguments filed 10/25/2010 have been fully considered but they are not persuasive.

Applicant argues that "the combination simply fails to disclose each and every limitation of the present invention and even if it were disclosed there is nothing in the combination of references to motivate the skilled artisan to look to the references to cure the deficiencies in the references, namely, that the combination of antioxidants in the claimed amounts and ratios are synergistic.

As stated in the prior response, the Office reviewed the previous rejection and calculated that Fleischner does in fact teach a flavonoid/vitamin E mixture in a weight ratio of from 40/60-90/10 percent, thus reading on the instant claims. *Since the flavonoid/vitamin E mixture is in fact present in a weight ratio from 40/60-90/100 percent, it is the examiner's understanding that the claimed antioxidant synergism affect would occur since the compounds are present in the claimed ratio.* This also applies to the applicant's arguments about how they fail to understand how the office sees that it is within the knowledge of one with ordinary skill in the art to modify the percentage of a nutrient/& types of nutrients in an ingredient/supplement for the desired effect(advisory action dated 10/12/2010), since the synergistic effect is not unexpected as would be inherent in Fleischner.

Applicant also argues that the combination of references do not provide a motivation for combining the specific combination of ingredients claimed herein. The examiner

disagrees. CHO teaches of a dietary supplement which contains grape seed extract, tocopherol (vitamin E), ascorbic acid (vitamin C) (paragraph 0028), polyphenols (paragraph 0004), and flavanols (paragraph 0005). This means that the supplement in CHO contains all the vitamin supplements claimed in the instant invention. CHO et al. also provides a motivation to combine antioxidant elements in a dietary supplement. This reason is that, there is a need for pharmacologic and nutritional interventions that are useful for preventing the reoccurrence of conditions such as coronary artery disease"(paragraph 0003).

In the instant application, the applicant is claiming an antioxidant composition/supplement where composition components are taken from difference sources (green tea, bush plum pulp, grape seed extract). Since it is known as shown from FLEISCHNER, BRAND, and CHO that these vitamins(C, E), polyphenols, and flavanols are inherently present in the plant sources of green tea, bush plum pulp, and grape seed extract, & it is also known to combine antioxidants(vitamins E,C, polyphenols, & flavanols) into a supplement, the examiner is under the understanding that it would be obvious to one of ordinary skill in the art to take the antioxidants from their known plant sources to form a composition. Therefore, the rejection is maintained.

### **Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to REBECCA FRITCHMAN whose telephone number is (571)270-5542. The examiner can normally be reached on Monday- Friday 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kim, Vickie can be reached on 571-272-0579. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

R.F.

/Krishnan S Menon/  
Primary Examiner, Art Unit 1777